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Circular Letter DHCQ: 06-6-461

TO: Chief Executive Officers, Acute Care Hospitals

FROM: Paul Dreyer, Ph.D., Associate Commissioner, Center for Quality Assurance and Control

DATE: June 20, 2006

RE: Amendments to 105 CMR 130.000 *Hospital Licensure*
Governing Maternal and Newborn Services

The purpose of this letter is to advise you of amendments to 105 CMR 130.000, *Hospital Licensure,* which became effective March 10, 2006. The amendments update, clarify and strengthen current sections of the regulations regarding requirements for hospital maternal and newborn care and standardize the definitions and service requirements for the various levels of care. The amendments incorporate the principles of national recommendations of care modified to the Massachusetts health care system and recognize advances in clinical practice that support quality of care. The amendments are consistent with the Department's goal to ensure mothers, newborns and their families have access to and receive quality care. Recognizing the scope and complexity of these regulations, we will not begin to survey for compliance immediately, thus providing hospitals an opportunity to come into compliance with the new regulations. We enclose a copy of the amended regulations and will be sending an application package to each hospital for renewal of the Maternal and Newborn Service designation shortly.

The amendments represent the collaborative efforts of the Department's Center for Community Health and Center for Quality Assurance and Control. For almost two years, the Department has been working with clinicians, hospitals, professional organizations and consumers to revise hospital licensure regulations governing maternal and newborn services. With the advice of these individuals, organizations, the Perinatal Regulation Revision Task Force and several working groups, the Department developed draft amendments that were presented for public comment.

Noted below is a summary of the key changes to the hospital licensure regulations.

<u>Level of Care Definitions and Requirements: Establishment of a Level II B Service Category</u>

The amendments add a Level II B community-based Maternal and Newborn Service that would provide a special care nursery service with the staff, services and facilities to care for newborns requiring Continuous Positive Airway Pressure (CPAP) in accordance with Department

guidelines. Department guidelines were already in place for CPAP waivers and were incorporated into the regulations by reference.

As in the previous regulations, all newborns requiring mechanical ventilation must be transferred to a Level III service. However, the hospital licensure regulations include a provision for the Department to allow special projects (105 CMR 130.051). Under these provisions, a Level II B service may apply to the Department for special project approval to provide Short Term Mechanical Ventilation (STMV). We expect to work with the Department's Perinatal Advisory Committee to develop stringent STMV guidelines and a special project review process that will include requirements for data collection, reporting and monitoring systems.

Volume Requirements

The previous regulations set minimum birth volume requirements for designation of a maternal and newborn service as a Level I B or Level II service.

Level I B: We eliminated the birth volume requirement for a Level I B service. A Level I B service includes a continuing care nursery service specially equipped and staffed to provide care to mild to moderately ill neonates born at that hospital or retro-transferred who do not require special care or intensive care services.

Level II: We retained the birth volume requirement for Level II services. Level IIA services (Level II in the previous regulations) will continue to need 1500 births annually for designation. The new designation of Level II B services will need 2000 births annually. This number of births is consistent with the current volume required in guidelines for Level II units with CPAP waivers. We have added a provision that allows the Department to designate a Level II service that does not meet the volume standard, if the service satisfactorily demonstrates that it meets all quality and competency standards.

Level III: We added a minimum birth volume requirement of 2000 annual births for a Level III service. The volume is consistent with the Level II B service. The amendments also include an alternative to volume that allows a service that does not meet the volume standard to demonstrate instead that its percentage of low birth weight infants is at least ten percent of total annual births.

Gestational Age

The regulations include gestational age in the definitions of various levels of maternal and newborn care in order to align care and services requirements with the needs of infants. Gestational age is one indicator of the level of risk and the type of services that patients may need. The definitions include gestational age as a tool to set the anticipated staff, services and facilities required for safe care. Level I services should have the capacity to care for maternal patients judged unlikely to deliver before 35 weeks gestation; Level II A, 34 weeks; Level II B, 32 weeks and Level III, all gestational ages.

Data Collection and Reporting

In order to better monitor infant morbidity and create population-based comparisons of outcomes, the Department amendments strengthen the requirements for data collection of certain maternal and infant indicators. The Department will develop the indicators in consultation with the Perinatal Advisory Committee.

In order to further strengthen the reporting requirements for the sickest neonates, we added a requirement that Level III maternal and newborn services participate in the Vermont Oxford Network Very Low Risk Database. Vermont Oxford Network is a non-profit voluntary collaboration of health care professionals dedicated to improving the quality and safety of medical

care of newborn infants and their families. Established in 1988, the Network is today comprised of over 485 Neonatal Intensive Care Units.

The Database includes information about the care and outcomes of high-risk newborns. The Database provides unique, reliable and confidential data to participating units for use in quality management, process improvement, internal audit and peer review.

Breastfeeding Support

The revisions include a requirement for lactation support to new mothers. At a minimum, each hospital shall provide every mother and infant requiring advanced lactation support with ongoing consultation during the hospital stay from an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience. The Department plans to evaluate the hospital's lactation support program to ensure that the Lactation Consultant who does not possess the IBCLC credential is an individual with advanced training, demonstrated experience in breastfeeding management and counseling, and has ongoing continuing education.

Miscellaneous Amendments

Other key provisions in the amendments:

- Update infection control requirements.
- Update physical plant requirements.
- Enhance collaboration/transfer agreement sections.
- Require Neonatal Intensive Care Units to have an in-house neonatologist 24 hours a day, who is either board certified or an active candidate for certification.
- Establish higher levels of certification, education, and/or experience requirements for physicians, nurses, respiratory therapists, pharmacists and nutritionists in Level II and III services.
- Require a board-certified or eligible family practitioner or pediatrician in Level IA service.
- Require an in-house obstetrician and neonatologist 24 hours a day in a Level III service.
- Require a designated nurse educator at all levels.

If you have any questions about the regulations please contact Ms. Gail Palmeri at gail.palmeri@state.ma.us or 617-753-8230, or Ms. Karin Downs at 617-624-5967 or karin.downs@state.ma.us

Attachment